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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/503,758	02/14/00	THILLY	W 2909.1000-00

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LEXINGTON MA 02421-4799

EXAMINER

EINSMANN, J

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/503,758

Applicant(s)

THILLY, WILLIAM G.

Examiner

Juliet C. Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

This action is written in response to the correspondence submitted 1/19/01. Claim 26 was amended and claim 60 was added. Claims 1-60 are pending. Upon further consideration, and in light of applicant's comments in the correspondence, further restriction as follows is required.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22 and 54, drawn to methods for identifying inherited point mutations, classified in class 435, subclass 6.
 - II. Claims 23, 25-28, 33, 59, and 60, drawn to methods for identifying genes with harmful alleles, classified in class 435, subclass 6.
 - III. Claims 24, 29-32, 34, and 55-56, drawn to nucleic acids complimentary to a strand of a gene or allele identified by the methods of group II, classified in class 536, subclass 23.1.
 - IV. Claims 35, 37, and 59, drawn to methods for identifying alleles that are a secondary risk factor that accelerate the appearance of the disease, classified in class 435, subclass 6.
 - V. Claims 36, 38 and 55-56 drawn to nucleic acids complimentary to a strand of a gene or allele identified by the methods of group IV, classified in class 536, subclass 23.1.
 - VI. Claims 39, 41, 43, and 59, drawn to methods for the detection of alleles which increase longevity, classified in class 435, subclass 6.

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- VII. Claims 40, 42, 44, and 55-56 drawn to nucleic acids complimentary to a strand of a gene or allele identified by the methods of group VI, classified in class 536, subclass 23.1.
- VIII. Claims 45, 46, and 59, drawn to methods for the detection of alleles which affect the incidence of disease, classified in class 435, subclass 6.
- IX. Claims 47, 55 and 56 drawn to nucleic acids complimentary to a strand of a gene or allele identified by the methods of group complimentary to a strand of a gene or allele identified by the methods of group VIII, classified in class 536, subclass 23.1.
- X. Claims 48, 50, 51, and 52, drawn to methods for the detection of deleterious alleles, classified in class 435, subclass 6.
- XI. Claims 49 and 53, and 55-56, drawn to nucleic acids complimentary to a strand of a gene or allele identified by the methods of group X, classified in class 536, subclass 23.1.
- XII. Claims 55 and 56 drawn to nucleic acids isolated by the method of group I, classified in class 536, subclass 23.1.
- XIII. Claims 57 and 58 drawn to arrays of isolated nucleic acids, classified in class 536, subclass 23.1.
- XIV. Claim 59, drawn a method for identifying inherited point mutations which interfere with reproduction, classified in class 435, subclass 6.

NOTE: Claim 59 and claims 55-56 are included in more than one group, because this claim encompasses multiple distinct inventions. In the event that a group which contains any of these claims is elected, the claims will be examined in so far as

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they pertain to the elected subject matter. Prior to allowance, amendment of the claim to be of the same scope of the elected subject matter will be required.

Claims 51 and 52 are drawn so as to appear that they depend from method claims, but claim 32 from which they actually depend is a product claim. They have been grouped with method claims, but amendment of these claims is necessary prior to examination.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is unrelated to the methods of inventions II, IV, VI, VIII, X, and XIV.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods which have different goals, use different reagents and comprise distinct process steps.

3. Inventions I and III, inventions I and V, inventions I and VII, and inventions I and IX, inventions I and XI, inventions I and XII, inventions I and XIII, inventions II and III, inventions IV and V, inventions VI and VII, inventions VIII and IX, and inventions X and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acids of invention III, V, VII, IX, XI, XII, XIII can be made by materially different processes such as by chemical synthesis or by other mutation detection processes.

4. The methods of inventions II, IV, VI, VII, X, and XIV are distinct from one another because they all have distinct goals, and are directed at identifying alleles with different effects. The methods require the examination of mutations from different populations, and require

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looking for different changes in the populations. For example the methods of invention II are drawn for the detection of harmful alleles and require examining young and old populations, and looking for a decrease in the frequency of a mutation, while the methods of invention IV require looking at populations of sick individuals who have early and late onset of a disease and comparing the frequency of point mutations in these populations. The searches required for examining each of these groups is therefore separate and distinct, requiring the use of different key words and databases.

5. The nucleic acids of groups III, V, VII, IX and XI are unrelated because they are all nucleic acids with distinct effects on humans. The nucleic acids of group III for example comprise harmful alleles that decrease in frequency as a population ages, while the nucleic acids of group V comprise alleles that are a risk factor which accelerates the onset of a disease.

6. The nucleic acids of groups III, V, VII, IX and XI are related to group XII in so far as group XII contains nucleic acids that have alleles included in groups III, V, VII, IX, and XI. In this case the nucleic acids of group XII are distinct from the other groups in that they would have different structures, functions, and utilities.

7. The nucleic acids of groups III, V, VII, IX, XI and XII are related to the arrays of group XIII as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the arrays do not specify all of

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the possible members of the array. The subcombination has separate utility such as using the nucleic acids as probes for the effects to which they are linked.

8. The remaining pairs of inventions are unrelated. Each of these pairs is comprised of a method for identifying a specific type of point mutation and nucleic acids which are found by different methods. The products are not the result of, nor necessary for the methods. Therefore these inventions are separate and distinct.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and/or recognized divergent subject matter and because inventions I-XIV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

10. A telephone call was made to Bob Underwood on 3/22/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Juliet C. Einsmann can be reached on (703) 308-1152. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Einsmann
Examiner
Art Unit 1655

March 23, 2001



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

3/23/01